



General

Guideline Title

Menopausal hormone therapy for the primary prevention of chronic conditions: U.S. Preventive Services Task Force recommendation statement.

Bibliographic Source(s)

U.S. Preventive Services Task Force. Menopausal hormone therapy for the primary prevention of chronic conditions: U.S. Preventive Services Task Force recommendation statement. Ann Intern Med. 2013 Jan 1;158(1):47-54. [28 references] [PubMed](#)

Guideline Status

This is the current release of the guideline.

This release updates a previously published guideline: U.S. Preventive Services Task Force. Hormone therapy for the prevention of chronic conditions in postmenopausal women: recommendations from the U.S. Preventive Services Task Force. Ann Intern Med 2005 May 17;142(10):855-60.

Recommendations

Major Recommendations

The U.S. Preventive Services Task Force (USPSTF) grades its recommendations (A, B, C, D, or I) and identifies the levels of certainty regarding net benefit (High, Moderate, and Low). The definitions of these grades can be found at the end of the "Major Recommendations" field.

Summary of Recommendations and Evidence

The USPSTF recommends against the use of combined estrogen and progestin for the prevention of chronic conditions in postmenopausal women. (This is a D recommendation.)

The USPSTF recommends against the use of estrogen for the prevention of chronic conditions in postmenopausal women who have had a hysterectomy. (This is a D recommendation.)

This recommendation applies only to postmenopausal women who are considering hormone therapy for the primary prevention of chronic medical conditions. This is not a recommendation about the use of hormone therapy to treat menopausal symptoms, such as hot flashes or vaginal dryness; the USPSTF did not review the evidence related to this possible indication because it falls outside of the mission and scope of the USPSTF. This recommendation also does not apply to women younger than 50 years who have had surgical menopause.

Clinical Considerations

Patient Population Under Consideration

This recommendation applies only to postmenopausal women who are considering hormone therapy for the primary prevention of chronic medical conditions. It does not apply to women who are considering hormone therapy for the management of menopausal symptoms, such as hot flashes or vaginal dryness. It also does not apply to women younger than 50 years who have had surgical menopause.

Assessment of Risk

This recommendation applies to the average-risk population. Risk factors for a specific chronic disease or individual characteristics that affect the likelihood of having a specific therapy-associated adverse event may cause a woman's net balance of benefits and harms to differ from that of the average population.

Use of Preventive Medication

Although combined estrogen and progestin therapy decreases the risk for fractures in postmenopausal women (about 46 fractures of any type prevented per 10,000 person-years), there is an accompanying increased risk for serious adverse events, such as stroke, invasive breast cancer, dementia, gallbladder disease, deep vein thrombosis (DVT), and pulmonary embolism (see Table 1 in the original guideline document). It does not decrease a woman's risk for coronary heart disease (CHD), and results from the Women's Health Initiative (WHI) randomized, controlled trial show a trend toward an increased likelihood of having a cardiac event (hazard ratio [HR], 1.22 [95% confidence interval (CI), 0.99 to 1.51]).

Estrogen-only therapy is associated with a reduction in the risk for fractures (about 56 fractures of any type prevented per 10,000 person-years), as well as a small reduction in the risk for invasive breast cancer (about 8 fewer cases per 10,000 person-years) and for dying of the disease (about two fewer deaths per 10,000 person-years) (see Table 2 in the original guideline document). The biological mechanism underlying the apparent protective effect of estrogen alone, as compared with the harmful effect of estrogen and progestin combined, on the development of invasive breast cancer in postmenopausal women is unclear. However, estrogen-only therapy is also associated with important harms, such as an increased likelihood of stroke, DVT, and gallbladder disease. It does not reduce the risk for CHD (WHI results: HR, 0.95 [CI, 0.78 to 1.15]).

In addition to other harms, combined oral estrogen and progestin and oral estrogen-only therapy have both been shown to be associated with an increased incidence of stress, mixed, or any urinary incontinence in previously asymptomatic women after 1 year. This outcome was measured by a self-administered questionnaire; additional randomized trials that focus on urinary incontinence as a primary study end point and use urodynamic testing as part of the assessment strategy would be useful to further clarify the effect of hormone therapy on urinary symptoms.

U.S. Food and Drug Administration (FDA)-approved indications for hormone therapy in postmenopausal women are limited to the treatment of menopausal symptoms and the prevention of osteoporosis. A black box warning indicates that estrogen with or without progestin should be prescribed at the lowest effective dose and for the shortest duration of use consistent with treatment goals and risks for the individual woman.

Timing of Intervention

No randomized trials have prospectively evaluated the effect of the timing of initiation of hormone therapy relative to menopause onset on associated benefits and harms. Post hoc subgroup analyses suggest an increased probability of harm with increasing age at initiation and longer duration of use, but these findings are not consistent across all trials and generally do not reach statistical significance.

Other Approaches to Prevention

Women have different characteristics and risk factors, such as age, family history, and comorbid medical conditions, that affect their likelihood of developing a given chronic disease; they may also differentially value preventing specific outcomes. As such, any choice of therapy should be based on the intersection of a woman's clinical situation, preferences, and values to maximize benefits over harms.

In the case of fractures, other effective interventions for treating women with low bone density include weight-bearing exercise, bisphosphonates, and calcitonin (the USPSTF addressed screening for osteoporosis in 2011). In women at high risk for breast cancer, the use of tamoxifen or raloxifene could potentially be a preventive strategy in selected situations, depending on the woman's underlying risk for stroke and thrombotic events. In addition to breast cancer chemoprevention and screening for osteoporosis, the USPSTF has issued recommendations on other relevant interventions for the primary or secondary prevention of chronic diseases in women, including medications for cardiovascular disease and screening for CHD, high blood pressure, lipid disorders, colorectal cancer, breast cancer, and dementia. All are available at www.uspreventiveservicestaskforce.org .

Definitions:

What the U.S. Preventive Services Task Force (USPSTF) Grades Mean and Suggestions for Practice

Grade	Grade Definitions	Suggestions for Practice
A	The USPSTF recommends the service. There is high certainty that the net benefit is substantial.	Offer or provide this service.
B	The USPSTF recommends the service. There is high certainty that the net benefit is moderate or there is moderate certainty that the net benefit is moderate to substantial.	Offer or provide this service.
C	<i>Note: The following statement is undergoing revision.</i> Clinicians may provide this service to selected patients depending on individual circumstances. However, for most individuals without signs or symptoms there is likely to be only a small benefit from this service.	Offer or provide this service only if other considerations support offering or providing the service in an individual patient.
D	The USPSTF recommends against the service. There is moderate or high certainty that the service has no net benefit or that the harms outweigh the benefits.	Discourage the use of this service.
I Statement	The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of the service. Evidence is lacking, of poor quality, or conflicting, and the balance of benefits and harms cannot be determined.	Read the "Clinical Considerations" section of USPSTF Recommendation Statement (see the "Major Recommendations" field). If the service is offered, patients should understand the uncertainty about the balance of benefits and harms.

USPSTF Levels of Certainty Regarding Net Benefit

Definition: The USPSTF defines *certainty* as "likelihood that the USPSTF assessment of the net benefit of a preventive service is correct." The net benefit is defined as benefit minus harm of the preventive service as implemented in a general, primary care population. The USPSTF assigns a certainty level on the basis of the nature of the overall evidence available to assess the net benefit of a preventive service.

Level of Certainty	Description
High	The available evidence usually includes consistent results from well-designed, well-conducted studies in representative primary care populations. These studies assess the effects of the preventive service on health outcomes. This conclusion is therefore unlikely to be strongly affected by the results of future studies.
Moderate	<p>The available evidence is sufficient to determine the effects of the preventive service on health outcomes, but confidence in the estimate is constrained by factors such as:</p> <ul style="list-style-type: none"> • The number, size, or quality of individual studies • Inconsistency of findings across individual studies • Limited generalizability of findings to routine primary care practice; and • Lack of coherence in the chain of evidence <p>As more information becomes available, the magnitude or direction of the observed effect could change, and this change may be large enough to alter the conclusion.</p>
Low	<p>The available evidence is insufficient to assess effects on health outcomes. Evidence is insufficient because of:</p> <ul style="list-style-type: none"> • The limited number or size of studies • Important flaws in study design or methods • Inconsistency of findings across individual studies • Gaps in the chain of evidence • Findings that are not generalizable to routine primary care practice; and • A lack of information on important health outcomes

Level of Description	More information may allow an estimation of effects on health outcomes.
Certainty	

Clinical Algorithm(s)

None provided

Scope

Disease/Condition(s)

Chronic conditions including:

- Cardiovascular events, such as coronary heart disease and stroke
- Breast cancer and colorectal cancer
- Fractures
- Cognitive function
- Thromboembolic events, such as deep vein thrombosis
- Gallbladder disease
- Urinary incontinence
- Diabetes

Guideline Category

Prevention

Clinical Specialty

Family Practice

Internal Medicine

Obstetrics and Gynecology

Preventive Medicine

Intended Users

Advanced Practice Nurses

Allied Health Personnel

Health Care Providers

Nurses

Physician Assistants

Physicians

Guideline Objective(s)

To update the 2005 U.S. Preventive Services Task Force (USPSTF) recommendation statement on hormone therapy for the prevention of chronic conditions in postmenopausal women

Target Population

Postmenopausal women who are considering hormone therapy for the primary prevention of chronic medical conditions

Note: These recommendations do not apply to women who are considering hormone therapy for the management of menopausal symptoms, such as hot flashes or vaginal dryness, or women younger than 50 years who have had surgical menopause.

Interventions and Practices Considered

Hormone replacement therapy (HRT):

- Combined estrogen and progestin (considered but not recommended)
- Estrogen alone (considered but not recommended)

Major Outcomes Considered

Key Question 1: What are the benefits of menopausal hormone therapy when used to prevent chronic conditions?

Key Question 2: What are the harms of menopausal hormone therapy when used to prevent chronic conditions?

Key Question 3: Do benefits and harms differ by subgroups? Subgroups include women with premature menopause; women with surgical menopause; age of use; types, doses, and modes of delivery of hormones; and presence of comorbidities.

Methodology

Methods Used to Collect/Select the Evidence

Hand-searches of Published Literature (Primary Sources)

Hand-searches of Published Literature (Secondary Sources)

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

Note from the National Guideline Clearinghouse (NGC): A systematic evidence review was prepared by the Oregon Evidence-based Practice Center (EPC) for use by the U.S. Preventive Services Task Force (USPSTF); see the "Availability of Companion Documents" field.

Data Sources and Searches

In conjunction with a research librarian, Evidence-based Practice Center (EPC) staff searched the Cochrane Central Register of Controlled Trials and Cochrane Database of Systematic Reviews (through the third quarter of 2011), MEDLINE (2002 to 30 November 2011), reference lists of articles, and SCOPUS for relevant English-language studies and systematic reviews.

Study Selection

Reviewers selected studies on the basis of inclusion and exclusion criteria developed for each key question. For all key questions, only randomized, controlled trials of postmenopausal hormone therapy versus placebo were included. Observational studies were not included because of the existence of published randomized trials designed to address the key questions directly and the known biases inherent in observational studies of menopausal hormone use. Trials were included that matched the target population, evaluated the primary prevention of new conditions rather than treatment of existing conditions, and provided risk reduction or elevation estimates for hormone therapy compared with placebo. Estimates for individual hormone therapy regimens were included and estimates that pooled results from different regimens were excluded. For trials that enrolled women with preexisting conditions, such as coronary heart disease (CHD) in the Heart and Estrogen/Progestin Replacement

Study (HERS), data were used for all outcomes except preexisting conditions and related conditions.

For trials that reported outcomes at various times, results appropriate to specific outcome measures were selected. For conditions known to be related to ongoing exposure to hormone therapy, such as thromboembolic disease and osteoporotic fractures, results reported at the end of the trial intervention phase. For conditions that were initiated during exposure but continued after the intervention phase, such as cancer, results reported at the end of the trial's postintervention phase were used, if available. The review team reviewed their selection of results from the Women's Health Initiative (WHI) trials with the WHI investigators.

Number of Source Documents

Out of 704 full-text articles reviewed for relevance to key questions, 51 full-text articles from 9 trials met inclusion criteria. An article with new results from the Women's Health Initiative (WHI) that was published after the literature search was also included.

Methods Used to Assess the Quality and Strength of the Evidence

Expert Consensus

Rating Scheme for the Strength of the Evidence

Not applicable

Methods Used to Analyze the Evidence

Systematic Review with Evidence Tables

Description of the Methods Used to Analyze the Evidence

Note from the National Guideline Clearinghouse (NGC): A systematic evidence review was prepared by the Oregon Evidence-based Practice Center (EPC) for use by the U.S. Preventive Services Task Force (USPSTF); see the "Availability of Companion Documents" field.

Data Extraction and Quality Assessment

From the included studies, an investigator abstracted details of the patient population, study design, analysis, follow-up, and results. Key data elements were confirmed by a second investigator. By using predefined criteria developed by the USPSTF for randomized trials, two investigators independently rated the quality of studies (good, fair, or poor) and resolved discrepancies by consensus.

Data Synthesis and Analysis

The Evidence-based Practice Center review team used results from the Women's Health Initiative (WHI) trials, including the main trials, the Women's Health Initiative Memory Study (WHIMS), and the Women's Health Initiative Study of Cognitive Aging (WHISCA), as the main estimates for each outcome rather than perform meta-analysis of all trials because the trials were heterogeneous, they were most applicable to the key questions, and their results would dominate the meta-analysis because of their large enrollment. As a group, the research team used methods developed by the USPSTF to assess the overall quality of the body of evidence for each key question (good, fair, or poor) on the basis of the number, quality, and size of studies; consistency of results between studies; and directness of evidence.

Methods Used to Formulate the Recommendations

Balance Sheets

Expert Consensus

Description of Methods Used to Formulate the Recommendations

Note from the National Guideline Clearinghouse (NGC): A systematic evidence review was prepared by the Oregon Evidence-based Practice Center (EPC) for use by the U.S. Preventive Services Task Force (USPSTF); see the "Availability of Companion Documents" field.

The U.S. Preventive Services Task Force (USPSTF) systematically reviews the evidence concerning both the benefits and harms of widespread implementation of a preventive service. It then assesses the certainty of the evidence and the magnitude of the benefits and harms. On the basis of this assessment, the USPSTF assigns a letter grade to each preventive service signifying its recommendation about provision of the service (see Table below). An important, but often challenging, step is determining the balance between benefits and harms to estimate "net benefit" (that is, benefits minus harms).

Table 1. U.S. Preventive Services Task Force Recommendation Grid*

Certainty of Net Benefit	Magnitude of Net Benefit			
	Substantial	Moderate	Small	Zero/Negative
High	A	B	C	D
Moderate	B	B	C	D
Low	Insufficient			

*A, B, C, D, and I (*Insufficient*) represent the letter grades of recommendation or statement of insufficient evidence assigned by the U.S. Preventive Services Task Force after assessing certainty and magnitude of net benefit of the service (see the "Rating Scheme for the Strength of the Recommendations" field).

The overarching question that the Task Force seeks to answer for every preventive service is whether evidence suggests that provision of the service would improve health outcomes if implemented in a general primary care population. For screening topics, this standard could be met by a large randomized, controlled trial (RCT) in a representative asymptomatic population with follow-up of all members of both the group "invited for screening" and the group "not invited for screening."

Direct RCT evidence about screening is often unavailable, so the Task Force considers indirect evidence. To guide its selection of indirect evidence, the Task Force constructs a "chain of evidence" within an analytic framework. For each key question, the body of pertinent literature is critically appraised, focusing on the following 6 questions:

1. Do the studies have the appropriate research design to answer the key question(s)?
2. To what extent are the existing studies of high quality? (i.e., what is the internal validity?)
3. To what extent are the results of the studies generalizable to the general U.S. primary care population and situation? (i.e., what is the external validity?)
4. How many studies have been conducted that address the key question(s)? How large are the studies? (i.e., what is the precision of the evidence?)
5. How consistent are the results of the studies?
6. Are there additional factors that assist the USPSTF in drawing conclusions (e.g., presence or absence of dose–response effects, fit within a biologic model)?

The next step in the Task Force process is to use the evidence from the key questions to assess whether there would be net benefit if the service were implemented. In 2001, the USPSTF published an article that documented its systematic processes of evidence evaluation and recommendation development. At that time, the Task Force's overall assessment of evidence was described as good, fair, or poor. The Task Force realized that this rating seemed to apply only to how well studies were conducted and did not fully capture all of the issues that go into an overall assessment of the evidence about net benefit. To avoid confusion, the Task Force has changed its terminology. Whereas individual study quality will continue to be characterized as good, fair, or poor, the term *certainty* will now be used to describe the Task Force's assessment of the overall body of evidence about net benefit of a preventive service and the likelihood that the assessment is correct. Certainty will be determined by considering all 6 questions listed above; the judgment about certainty will be described as high, moderate, or low.

In making its assessment of certainty about net benefit, the evaluation of the evidence from each key question plays a primary role. It is important to note that the Task Force makes recommendations for real-world medical practice in the United States and must determine to what extent the evidence for each key question—even evidence from screening RCTs or treatment RCTs—can be applied to the general primary care population. Frequently, studies are conducted in highly selected populations under special conditions. The Task Force must consider differences between the general primary care population and the populations studied in RCTs and make judgments about the likelihood of observing the same effect in

actual practice.

It is also important to note that one of the key questions in the analytic framework refers to the potential harms of the preventive service. The Task Force considers the evidence about the benefits and harms of preventive services separately and equally. Data about harms are often obtained from observational studies because harms observed in RCTs may not be representative of those found in usual practice and because some harms are not completely measured and reported in RCTs.

Putting the body of evidence for all key questions together as a chain, the Task Force assesses the certainty of net benefit of a preventive service by asking the 6 major questions listed above. The Task Force would rate a body of convincing evidence about the benefits of a service that, for example, derives from several RCTs of screening in which the estimate of benefits can be generalized to the general primary care population as "high" certainty (see the "Rating Scheme for the Strength of Recommendations" field). The Task Force would rate a body of evidence that was not clearly applicable to general practice or has other defects in quality, research design, or consistency of studies as "moderate" certainty. Certainty is "low" when, for example, there are gaps in the evidence linking parts of the analytic framework, when evidence to determine the harms of treatment is unavailable, or when evidence about the benefits of treatment is insufficient. Table 4 in the methodology document listed below (see the "Availability of Companion Documents" field) summarizes the current terminology used by the Task Force to describe the critical assessment of evidence at all 3 levels: individual studies, key questions, and overall certainty of net benefit of the preventive service.

Sawaya GF et al. Update on the methods of the U.S. Preventive Services Task Force: estimating certainty and magnitude of net benefit. *Ann Intern Med.* 2007;147:871-875.[5 references].

Rating Scheme for the Strength of the Recommendations

What the U.S. Preventive Services Task Force (USPSTF) Grades Mean and Suggestions for Practice

Grade	Grade Definitions	Suggestions for Practice
A	The USPSTF recommends the service. There is high certainty that the net benefit is substantial.	Offer or provide this service.
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C	<i>Note: The following statement is undergoing revision.</i> Clinicians may provide this service to selected patients depending on individual circumstances. However, for most individuals without signs or symptoms there is likely to be only a small benefit from this service.	Offer or provide this service only if other considerations support offering or providing the service in an individual patient.
D	The USPSTF recommends against the service. There is moderate or high certainty that the service has no net benefit or that the harms outweigh the benefits.	Discourage the use of this service.
I Statement	The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of the service. Evidence is lacking, of poor quality, or conflicting, and the balance of benefits and harms cannot be determined.	Read the "Clinical Considerations" section of USPSTF Recommendation Statement (see the "Major Recommendations" field). If the service is offered, patients should understand the uncertainty about the balance of benefits and harms.

USPSTF Levels of Certainty Regarding Net Benefit

Definition: The USPSTF defines *certainty* as "likelihood that the USPSTF assessment of the net benefit of a preventive service is correct." The net benefit is defined as benefit minus harm of the preventive service as implemented in a general, primary care population. The USPSTF assigns a certainty level on the basis of the nature of the overall evidence available to assess the net benefit of a preventive service.

Level of Certainty	Description
High	The available evidence usually includes consistent results from well-designed, well-conducted studies in representative primary care populations. These studies assess the effects of the preventive service on health outcomes. This conclusion is therefore unlikely to be strongly affected by the results of future studies.
Moderate	<p>The available evidence is sufficient to determine the effects of the preventive service on health outcomes, but confidence in the estimate is constrained by factors such as:</p> <ul style="list-style-type: none"> • The number, size, or quality of individual studies • Inconsistency of findings across individual studies • Limited generalizability of findings to routine primary care practice; and • Lack of coherence in the chain of evidence <p>As more information becomes available, the magnitude or direction of the observed effect could change, and this change may be large enough to alter the conclusion.</p>
Low	<p>The available evidence is insufficient to assess effects on health outcomes. Evidence is insufficient because of:</p> <ul style="list-style-type: none"> • The limited number or size of studies • Important flaws in study design or methods • Inconsistency of findings across individual studies • Gaps in the chain of evidence • Findings that are not generalizable to routine primary care practice; and • A lack of information on important health outcomes <p>More information may allow an estimation of effects on health outcomes.</p>

Cost Analysis

A formal cost analysis was not performed and published cost analyses were not reviewed.

Method of Guideline Validation

Comparison with Guidelines from Other Groups

External Peer Review

Internal Peer Review

Description of Method of Guideline Validation

Peer Review. Before the U.S. Preventive Services Task Force (USPSTF) makes its final determinations about recommendations on a given preventive service, the Evidence-based Practice Center and the Agency for Healthcare Research and Quality send a draft evidence review to 4 to 6 external experts and to Federal agencies and professional and disease-based health organizations with interests in the topic. The experts are asked to examine the review critically for accuracy and completeness and to respond to a series of specific questions about the document. After assembling these external review comments and documenting the proposed response to key comments, the topic team presents this information to the USPSTF in memo form. In this way, the USPSTF can consider these external comments before it votes on its recommendations about the service. Draft recommendation statements are then circulated for comment among reviewers representing professional societies, voluntary organizations, and Federal agencies, as well as posted on the Task Force Web site for public comment. These comments are discussed before the final recommendations are confirmed.

Responses to Public Comment. A draft version of this recommendation statement was posted for public comment on the USPSTF Web site from 29 May to 26 June 2012. In response to the comments received, the USPSTF clarified the populations to which the recommendations apply; the specific form, dosage, and route of administration of the estrogen and progestin and estrogen-only therapies considered; and the reasons for not

considering bioidentical hormone therapy.

Comparison with Guidelines from Other Groups. Recommendations from the following groups were discussed: The American Heart Association, the American Congress of Obstetricians and Gynecologists, the Canadian Task Force on Preventive Health Care, the American Academy of Family Physicians, and the North American Menopause Society.

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The type of supporting evidence is not specifically stated for each recommendation.

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

Combined Estrogen and Progestin

Many health outcomes potentially associated with the use of hormone therapy in postmenopausal women have been examined. The U.S. Preventive Services Task Force (USPSTF) found convincing evidence that estrogen and progestin therapy (specifically, oral conjugated equine estrogen, 0.625 mg/d, plus medroxyprogesterone acetate, 2.5 mg/d) is of moderate benefit in reducing the risk for fractures in postmenopausal women. Table 1 in the original guideline document provides absolute risk difference estimates for the benefits and harms of estrogen and progestin therapy.

Estrogen Alone

The use of estrogen without progestin has generally been restricted to women who have had a hysterectomy because unopposed estrogen use increases the risk for endometrial cancer in women with an intact uterus. The USPSTF found convincing evidence that estrogen (specifically, oral conjugated equine estrogen, 0.625 mg/d) is of moderate benefit in reducing the incidence of fractures. There is adequate evidence that the use of estrogen alone results in a small reduction in the risk for developing or dying of invasive breast cancer. There is convincing evidence that estrogen does not have a beneficial effect on coronary heart disease (CHD). Table 2 in the original guideline document provides absolute risk difference estimates for the benefits and harms of estrogen therapy.

Potential Harms

Combined Estrogen and Progestin

The U.S. Preventive Services Task Force (USPSTF) found adequate evidence that use of combined estrogen and progestin therapy is associated with moderate harms, including an increase in the risk for stroke, dementia, gallbladder disease, and urinary incontinence. There is convincing evidence of a small increase in the incidence of invasive breast cancer and adequate evidence of a small increase in breast cancer deaths. There is also convincing evidence that estrogen and progestin therapy is associated with a small increased risk for deep venous thrombosis (DVT) and pulmonary embolism. Convincing evidence shows that the use of estrogen and progestin therapy does not have a beneficial effect on coronary heart disease (CHD) and probably increases the risk for its occurrence. Table 1 in the original guideline document provides absolute risk difference estimates for the benefits and harms of estrogen and progestin therapy.

Estrogen Alone

The use of estrogen without progestin has generally been restricted to women who have had a hysterectomy because unopposed estrogen use increases the risk for endometrial cancer in women with an intact uterus. The USPSTF found adequate evidence that its use is associated with moderate harms, including the risk for stroke, gallbladder disease, and urinary incontinence, as well as a small increase in the risk for DVT. There is convincing evidence that estrogen does not have a beneficial effect on CHD. Table 2 in the original guideline document provides absolute risk difference estimates for the benefits and harms of estrogen therapy.

Qualifying Statements

Qualifying Statements

- The U.S. Preventive Services Task Force (USPSTF) makes recommendations about the effectiveness of specific clinical preventive services for patients without related signs or symptoms.
- It bases its recommendations on the evidence of both the benefits and harms of the service and an assessment of the balance. The USPSTF does not consider the costs of providing a service in this assessment.
- The USPSTF recognizes that clinical decisions involve more considerations than evidence alone. Clinicians should understand the evidence but individualize decision making to the specific patient or situation. Similarly, the USPSTF notes that policy and coverage decisions involve considerations in addition to the evidence of clinical benefits and harms.
- Recommendations made by the USPSTF are independent of the U.S. government. They should not be construed as an official position of the Agency for Healthcare Research and Quality or the U.S. Department of Health and Human Services.

Implementation of the Guideline

Description of Implementation Strategy

The experiences of the first and second U.S. Preventive Services Task Force (USPSTF), as well as that of other evidence-based guideline efforts, have highlighted the importance of identifying effective ways to implement clinical recommendations. Practice guidelines are relatively weak tools for changing clinical practice when used in isolation. To effect change, guidelines must be coupled with strategies to improve their acceptance and feasibility. Such strategies include enlisting the support of local opinion leaders, using reminder systems for clinicians and patients, adopting standing orders, and audit and feedback of information to clinicians about their compliance with recommended practice.

In the case of preventive services guidelines, implementation needs to go beyond traditional dissemination and promotion efforts to recognize the added patient and clinician barriers that affect preventive care. These include clinicians' ambivalence about whether preventive medicine is part of their job, the psychological and practical challenges that patients face in changing behaviors, lack of access to health care or of insurance coverage for preventive services for some patients, competing pressures within the context of shorter office visits, and the lack of organized systems in most practices to ensure the delivery of recommended preventive care.

Dissemination strategies have changed dramatically in this age of electronic information. While recognizing the continuing value of journals and other print formats for dissemination, the USPSTF Task Force will make all its products available through its [Web site](#) . The combination of electronic access and extensive material in the public domain should make it easier for a broad audience of users to access USPSTF materials and adapt them for their local needs. Online access to USPSTF products also opens up new possibilities for the appearance of the annual, pocket-size *Guide to Clinical Preventive Services*.

To be successful, approaches for implementing prevention have to be tailored to the local level and deal with the specific barriers at a given site, typically requiring the redesign of systems of care. Such a systems approach to prevention has had notable success in established staff-model health maintenance organizations, by addressing organization of care, emphasizing a philosophy of prevention, and altering the training and incentives for clinicians. Staff-model plans also benefit from integrated information systems that can track the use of needed services and generate automatic reminders aimed at patients and clinicians, some of the most consistently successful interventions. Information systems remain a major challenge for individual clinicians' offices, however, as well as for looser affiliations of practices in network-model managed care and independent practice associations, where data on patient visits, referrals, and test results are not always centralized.

Implementation Tools

Foreign Language Translations

Mobile Device Resources

Patient Resources

Pocket Guide/Reference Cards

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Staying Healthy

IOM Domain

Effectiveness

Patient-centeredness

Identifying Information and Availability

Bibliographic Source(s)

U.S. Preventive Services Task Force. Menopausal hormone therapy for the primary prevention of chronic conditions: U.S. Preventive Services Task Force recommendation statement. *Ann Intern Med.* 2013 Jan 1;158(1):47-54. [28 references] [PubMed](#)

Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

1996 (revised 2013 Jan 1)

Guideline Developer(s)

U.S. Preventive Services Task Force - Independent Expert Panel

Guideline Developer Comment

The U.S. Preventive Services Task Force (USPSTF) is a federally-appointed panel of independent experts. Conclusions of the USPSTF do not necessarily reflect policy of the U.S. Department of Health and Human Services (DHHS) or DHHS agencies.

Source(s) of Funding

The U.S. Preventive Services Task Force (USPSTF) is an independent, voluntary body. The U.S. Congress mandates that the Agency for Healthcare Research and Quality support the operations of the USPSTF.

Guideline Committee

Composition of Group That Authored the Guideline

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**Members of the USPSTF at the time this recommendation was finalized. For a list of current Task Force members, go to <http://www.uspreventiveservicestaskforce.org/Page/Name/our-members> .*

Financial Disclosures/Conflicts of Interest

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Guideline Status

This is the current release of the guideline.

This release updates a previously published guideline: U.S. Preventive Services Task Force. Hormone therapy for the prevention of chronic conditions in postmenopausal women: recommendations from the U.S. Preventive Services Task Force. *Ann Intern Med* 2005 May 17;142(10):855-60.

Guideline Availability

Electronic copies: Available from the [Annals of Internal Medicine Web site](#) .

Availability of Companion Documents

The following are available:

Evidence Reviews:

- Nelson HD, Walker M, Zakher B, Mitchell J. Menopausal hormone therapy for the primary prevention of chronic conditions: a systematic review to update the U.S. Preventive Services Task Force recommendations. *Ann Intern Med* 2012 Jul 17;157(2):104-13.
- Nelson HD, Walker M, Zakher B, Mitchell J. Menopausal hormone therapy for the primary prevention of chronic conditions: systematic review to update the 2002 and 2005 U.S. Preventive Services Task Force recommendations. Evidence synthesis no. 93. AHRQ publication no. 12-05168-EF-1. Rockville, MD: Agency for Healthcare Research and Quality; 2012.

Electronic copies: Available from the [U.S. Preventive Services Task Force \(USPSTF\) Web site](#) .

Background Articles:

- Barton MB et al. How to read the new recommendation statement: methods update from the U.S. Preventive Services Task Force. *Ann Intern Med* 2007;147:123-127.
- Guirgis-Blake J et al. Current processes of the U.S. Preventive Services Task Force: refining evidence-based recommendation development. *Ann Intern Med* 2007;147:117-122.
- Sawaya GF et al. Update on the methods of the U.S. Preventive Services Task Force: estimating certainty and magnitude of net benefit. *Ann Intern Med* 2007;147:871-875.

Electronic copies: Available from the [USPSTF Web site](#) .

The following are also available:

- Menopausal hormone therapy for the primary prevention of chronic conditions: clinical summary of U.S. Preventive Services Task Force recommendation. Rockville (MD): U.S. Preventive Services Task Force; 2012 Oct. Electronic copies: Available from the [USPSTF Web Site](#) .
- The guide to clinical preventive services, 2012. Recommendations of the U.S. Preventive Services Task Force. Rockville (MD): Agency for Healthcare Research and Quality (AHRQ); 2012. 128 p. Electronic copies: Available from the [AHRQ Web site](#) . See the related QualityTool summary on the [Health Care Innovations Exchange Web site](#) .

The [Electronic Preventive Services Selector \(ePSS\)](#) , available as a PDA application and a web-based tool, is a quick hands-on tool designed to help primary care clinicians identify the screening, counseling, and preventive medication services that are appropriate for their patients. It is based on current recommendations of the USPSTF and can be searched by specific patient characteristics such as age, sex, and selected behavioral risk factors.

Patient Resources

The following are available:

- Menopausal hormone therapy for the primary prevention of chronic conditions: understanding Task Force recommendations. U.S. Preventive Services Task Force. Consumer fact sheet. 2012 Oct. 4 p. Electronic copies: Available from the [U.S. Preventive Services Task Force Web site](#) .
- Women: stay healthy at any age. Rockville (MD): Agency for Healthcare Research and Quality. AHRQ Pub. No. 10-IP002-A. 2010 Aug. 2 p. Electronic copies: Available in Portable Document Format (PDF) in [English](#) and [Spanish](#) from the AHRQ Web site. See the related QualityTool summary on the [Health Care Innovations Exchange Web site](#) .

Print copies: Available in English and Spanish from the Agency for Healthcare Research and Quality (AHRQ) Publications Clearinghouse. For more information, go to <http://www.ahrq.gov/research/publications/index.html> or call 1-800-358-9295 (U.S. only).

Myhealthfinder is a new tool that provides personalized recommendations for clinical preventive services specific to the user's age, gender, and pregnancy status. It features evidence-based recommendations from the USPSTF and is available at www.healthfinder.gov .

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

NGC Status

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